

AMENDMENTS TO THE CLAIMS

SUB F1

Claim 1 (previously cancelled)

Claim 2 (previously amended)

The process according to claim 15, wherein validation of the final certification is conditional on input of a validation password with a computer.

Claim 3 (previously amended)

E1

The process according to claim 15, implemented in a data processing system, wherein with each validation step is associated at least one screen page

PO: a screen page which provides the process operator

PEI: screen page corresponding to a stage of a process number

EP: title

EA: retrospective analysis screen page

EC: certification screen page

EI: anomalies screen page

which can be accessed on a display means of at least one computer workstation connected to said data processing system.

Claim 4 (previously amended)

E2

The process according to claim 3, wherein each screen page comprises coded identification field for a patient which matches a batch of samples subjected to the standard operating procedure.

Claim 5 (previously amended)

E3

The process according to claim 15 wherein exit from certain stages (RA) of said process is conditional on printing the screen pages (EA) corresponding to these stages.

Claim 6 (previously amended)

The process according to claim 15 implemented in a preparation laboratory receiving therapeutic kits from at least one operational entity (EX), wherein it further comprises stages for monitoring the transfer of these kits.

E4

Claim 7 (previously amended)

The process according to claim 15 implemented in a preparation laboratory which deals with a cytapheresis service, wherein it further comprises stages for monitoring the receipt of cytapheresis pouches.

Claim 8 (previously amended)

E5

The process according to claim 15 implemented in a preparation laboratory which deals with a control laboratory, wherein it further comprises stages for processing results

E5

of control tests carried out on each batch of samples.

Claim 9 (previously cancelled)

Claim 10 (previously amended)

A system according to claim 16, implemented in a preparation laboratory, designed to execute management tasks of a preparation laboratory number n within this laboratory.

Claim 11 (previously amended)

A system according to claim 16, wherein it is connected to a communications network to exchange data with other entities selected from the group consisting of: treatment centers number n, cytopheresis services number n, collection centers number n and, bacteriological testing laboratories involved in a therapeutic process.

E6

Claim 12 (previously amended)

Application of the process and of an information processing system used for quality management according to claim 15 to cell therapy protocols.

Claim 13 (previously amended)

Application of the process and of an information processing system used for quality management according to claim 15 to gene therapy protocols.

Claim 14 (previously amended)

E6 Application of the process and of a quality management system according to claim 15, allowing ongoing training of the operator and/or the monitoring of his or her level of knowledge.

Claim 15 (currently amended)

E7 A method for processing information used for quality management in a therapeutic process involving several entities, ~~optionally remote~~, including an operational entity, ~~and a preparation laboratory remote from the operational entity, and a treatment center remote from the operational entity~~, this therapeutic process comprising operations of taking cells from a patient, specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for ~~preparing procedure for~~ preparation (SOP) comprising a series of functional stages,

€ characterized in that it comprises, for each batch of samples taken from a given patient;

- ~~after~~ each functional stage, followed by a stage of sequential and conditional validation of data collected during said functional stage, passing from one validation stage to a following validation stage being conditional on results of processing data collected during this validation stage and on a full completion by an operator of all critical points, and the entry of all required data within a screen page associated with said functional stage before moving to the next validation stage,

-a stage of processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being in particular indicative of operators and of the process state of progress, ~~in order~~ to issue final certification of a preparation ~~carried~~ carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation, a stage of inputting post-reinjection retrospective analysis information and a stage for ~~inputting~~ inputting post-reinjection follow-up information and forwarding said information to said operational entity.

Claim 16 (currently amended)

E7
~~System~~ A system for processing information used for quality management in a therapeutic process involving several entities, ~~optionally remote~~ including an operational entity, ~~and a preparation laboratory remote from the operational entity, and a treatment center remote from the operational entity,~~ this therapeutic process comprising operations of taking cells from a patient, specific treatment operations including cytapheresis, on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in ~~is~~ this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional stages,

characterized in that it comprises, for each batch of samples taken from a given patient:

NOT PART
OF SYSTEM

E7
for each functional stage, followed by a means of sequential and conditional validation of ~~said~~ data collected during said functional step-stage, passing from one validation stage to a following validation stage being conditional on results of processing of data collected during this validation stage and on a full completion by an operator of all critical points within a screen page associated with said functional stage, before moving to the next validation stage,

means for processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being indicative ~~in particular~~ of operators and of the process state of progress, ~~in order~~ to issue final certification of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation, ~~and~~

means for ~~inputting~~ inputting post-reinjection follow-up information and forwarding said information to said operational entity.